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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,424	11/03/2003	David W. Johnson	CALW-004/01US 306562-2009	1511
58249	7590	09/12/2011	EXAMINER	
COOLEY LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001			ROBINSON, KEITH O NEAL	
			ART UNIT	PAPER NUMBER
			1638	
			MAIL DATE	DELIVERY MODE
			09/12/2011	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,424	<b>Applicant(s)</b> JOHNSON ET AL.	
	<b>Examiner</b> KEITH ROBINSON	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 5) ☒ Claim(s) 2-4,6-19,30 and 31 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 2-4,6-19,30 and 31 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 03 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

Applicant's cancellation of claims 1, 5 and 20-29 and amendment of claims 15 and 18, filed June 24, 2011, have been received and entered in full.

Claims 2-4, 6-19, 30 and 31 are under examination.

### ***Response to Arguments***

Applicant's arguments, see page 7, paragraph I of 'Remarks' filed June 24, 2011, with regard to the 'Claim objection' on page 3 of the Office Action mailed March 25, 2011 have been fully considered and deemed persuasive. The objection has been withdrawn.

Applicant's arguments, see page 10, paragraph III of 'Remarks' filed June 24, 2011, with regard to the 35 USC § 102(b) rejection on pages 6-7 of the Office Action mailed March 25, 2011 have been fully considered and deemed persuasive. The rejection has been withdrawn.

Applicant's 'Terminal disclaimer' filed June 24, 2011 has been approved, thus obviating the 'Double patenting' rejection on pages 7-10 of the Office Action mailed March 25, 2011. The rejection has been withdrawn.

***Claim Rejections - 35 USC § 112, first paragraph – Written Description***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 2-4, 6-19, 30 and 31 remain rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims read on any *Medicago sativa* alfalfa variety comprising 'French' type alfalfa germplasm, wherein said variety has **8% or greater faster recovery after spring green-up or after harvest** compared to an adapted check variety selected from the group consisting of 'Wintergold' and 'Hybri-Force 400' and **15% or greater more erect stems at late bloom** compared to an adapted check variety selected from the group consisting of 'WL325HQ' and 'WL319HQ'.

The specification has not identified which conserved germplasm is associated with the faster recovery after spring green-up or after harvest trait. The specification discloses four exemplified varieties by crossing over 1000 undisclosed and uncharacterized "French lines" (see, for example, page 25, lines 3 and 15; page 29, lines 13-16 and page 30, line 3; page 35, lines 7 and 16; page 40, lines 3-12).

The specification, see, for example, page 16, Table 4, discloses that the alfalfa varieties Daisy, Diane, Europe (also known as Europa), Marshall and Mercedes; all

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previously identified as comprising “French-type germplasm”(see, for example, page 19, last paragraph to page 20, line 3 of 'Remarks' filed October 6, 2010), including at least one variety with 100% French-type germplasm (Europa, see page 26, Exhibit B of 'Remarks' filed October 6, 2010); have poorer recovery than the claimed control/check varieties when grown in North America.

Thus, the mere presence of “French-type germplasm” is not correlated with faster recovery after spring green-up.

In addition, a representative number of species of plants with the claimed characteristics has not been shown.

Furthermore, the specification has not identified which conserved germplasm is associated with the more erect stems at late bloom trait (i.e., standability). With regard to standability and French-type germplasm, the mere presence of French-type germplasm does not appear to be correlated with *significantly* higher standability when compared to the instantly claimed check varieties WL 325HQ and WL 319HQ. Page 20, second full paragraph of 'Remarks' filed June 21, 2006 states that Winter Gold has 47% Flemish (French) cytoplasm. Page 21 of that response, top paragraph, states that the variety 54V54 has greater than 27% Flemish cytoplasm. However, instant Tables 7a, 7b and 7d on pages 19, 20 and 22 show that each of these varieties has only *slightly* higher standability than the instantly claimed check varieties. Furthermore, a representative number of species of plants with the claimed characteristics has not been shown.

***Response to Arguments***

Applicant argues that there is no burden for the Applicant to show which portion of the 'French' type germplasm is contributing to the claimed characteristics and Applicant need only to show how to make and use the claimed invention (see page 7, paragraph II to page 8, lines 1-7 of 'Remarks' filed June 24, 2011).

This is not persuasive. The requirements of the written description is to describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116". Showing how to make and use the claimed invention is a requirement for enablement.

In addition, the Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material". *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

The claimed invention has not been adequately described because the specification does not provide a representative number of species of plants with the claimed characteristics and the mere presence of “French-type germplasm” is not correlated with faster recovery after spring green-up.

Applicant argues that the present application provides much detail regarding how to produce alfalfa varieties having the claimed phenotypes with ‘French’ types germplasm; thus, by following the methods described in the present application, one skilled in the art will surely be able to identify alfalfa varieties having the claimed characteristics without knowing exactly which portion of the ‘French’ type germplasm is contributing the claimed characteristics (see page 8, 2<sup>nd</sup> paragraph of ‘Remarks’ filed June 24, 2011).

This is not persuasive. The methods of how to make the claimed invention is not an adequate description of the claimed invention. As stated above, the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function.

Applicant argues that a representative number of different species of plants with the claimed characteristics has been shown in the present application, such as 'CW 75046', 'CW 83021', 'CW 85020' and 'CW 95026' (see page 8, last paragraph of 'Remarks' filed June 24, 2011).

This is not persuasive. The specification does not provide evidence of a representative number of species of plants with the claimed characteristics because not all of the exemplified varieties have both characteristics. For example, alfalfa variety 'CW 75046' has 9% faster recovery compared to an adapted check but does not have 15% or greater more erect stems at late bloom (see, for example, page 27, Table 8).

In addition, as discussed above, with regard to standability and French-type germplasm, the mere presence of French-type germplasm does not appear to be correlated with *significantly* higher standability when compared to the instantly claimed check varieties WL 325HQ and WL 319HQ. Page 20, second full paragraph of 'Remarks' filed June 21, 2006 states that Winter Gold has 47% Flemish (French) cytoplasm. Page 21 of that response, top paragraph, states that the variety 54V54 has

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greater than 27% Flemish cytoplasm. However, instant Tables 7a, 7b and 7d on pages 19, 20 and 22 show that each of these varieties has only *slightly* higher standability than the instantly claimed check varieties.

Applicant argues that one skilled in the art can use any of Applicant's inventive, disclosed and deposited alfalfa varieties to develop additional alfalfa varieties which meet the claimed limitations and that the 'Johnson Declaration' demonstrates that Applicant has done exactly this (see page 9, lines 3-15 of 'Remarks' filed June 24, 2011).

This is not persuasive. It is noted that the deposited lines are not claimed in the instant claims, but rather the broad genus of alfalfa plants having the claimed characteristics. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEITH ROBINSON whose telephone number is (571)272-2918. The examiner can normally be reached Monday – Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson

/KATHLEEN K BRAGDON/

Supervisory Patent Examiner, Art Unit 1600